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No. 935 625

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and Günther Bodendieck, Hamburg-Blankenese
are named as inventors

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Excision device

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The invention relates to an excision device with which tissue samples may be removed from the human body. The device may also be used to suction fluids, and to inject irrigation fluids and medications.

The excision device according to the invention comprises in its main section a needle (together with its back part designated as the needle part), and with a cover sleeve (together with its back part designated as the cover part), whereby the needle comprises a tube or a rod or the like that is provided with a tip section that is rounded, pointed, or knife-shaped, e.g., one-, two-, or multi-edged, with a beveled cutting edge as with injection needles or the like, and in addition is implemented with a cutout, notch, or opening or the like at its tip section for capturing tissue samples, while the tip section and the cutout or the like of the needle are implemented such that when the needle is inserted into the tissue, tissue must perforce enter into the cutout, which may be covered by the cover sleeve that is positioned at the needle in the direction of the longitudinal axis of same or rotated around the longitudinal axis of same, and whereby the tissue that protrudes into the cutout is cut by its cutting edges. The cover sleeve is comprised of a tube, a cylinder, a ridge, or the like. It is implemented at the tip section and is completely or partially able to cut, as required by the particular construction.

The cutout or the like of the needle is covered by the cover sleeve, which is slid along the needle in the direction of the longitudinal axis of same, or rotated or spiraled around the longitudinal axis of same, depending on the particular construction of the device, such that when the needle is stuck or inserted into the human body no tissue may be introduced into the cutout. The cutout is released only at the point in the body from which tissue is to be biopsied by retracting the cover sleeve or rotating it back. In this state, the needle is, depending on the

construction of the device, introduced a small distance further into the tissue or retracted or rotated back a corresponding distance, whereby the tissue is pushed into the cutout. In this state, the cutout is again covered by the cover sleeve, whereby the tissue that protrudes into the cutout is cut off. The needle with the tissue sample can then be removed. However, it may in this state be guided further into the tissue for the purpose of taking further samples. Depending on the construction of the device, the cover sleeve or the needle part may be removed by itself so that the device can then be used for irrigation, etc. The implementation of the tip section of the needle and the implementation of the cutout or the like of the needle may be contoured such that when the needle is inserted into tissue, tissue must perforce be introduced into at least a partial section of the cutout. The cover sleeve and the needle or the cover sleeve or the needle, respectively, are provided with cutting edges such that when the cutout or the like is covered the protruding tissue is cut off cleanly.

The particular advantage of the excision device is that it enables one to remove an unadulterated and, in particular, an uncrushed piece of tissue from each part of the body, and in particular from every part of the body because the needle of the device may be manufactured with the smallest diameter, and because in addition it leaves the smallest possible puncture wound. Such a device enables one easily to biopsy tissue samples, e.g., from the heart muscle or from the liver. This is not possible with the customary complicated Silverman needle. It causes a larger puncture wound because biopsy spoons spread apart. Furthermore, the tissue to be biopsied is crushed when the spoons come back together.

The needle may be produced with the smallest diameter because its construction is the simplest imaginable. The cover sleeve is slid along the needle, in other words parallel to the longitudinal axis of the needle, whereby it may be freely movable or positively actuated. With a straight needle, an implementation may be selected such that the cover sleeve for the purpose of cutting the tissue biopsy must be rotated or, depending on the construction of the device, slid in a spiral or similar manner, without thereby rendering the device considerably more complicated. Because the cover sleeve is slid along the needle or along the needle part, it is possible to implement it up to the handle parts of the device. It may, however, be of a part with its handle part, just like the needle.

The device is generally comprised in its entirety of only two parts, the needle and the cover sleeve that may be introduced into the human body for the purpose of biopsying tissue. Both parts may therefore interact when advantageously contoured, achieving the highest level of stability. The device may in practice be implemented with a needle, the diameter of which is equal to that of the thinnest injection needle.

An exemplary embodiment of the invention is illustrated by the following diagrams.

Figure 1 shows an excision device with extractor in part in cross-section;

Figures 2, 3, 4, 5, and 6 shows the excision device broken down into its main components;

Figures 7, 8, and 9 show enlargements of various views of the needle tip of the device in the state in which tissue may protrude into the cutout;

Figure 10 shows a cross-section along line *A-A*;

Figure 11 shows a variant;

Figure 12 shows a cross-section along line *B-B*;

Figure 13 shows an excision device in part in cross-section in which the needle has a recess or an opening, respectively; the cover sleeve is adjustable;

Figure 14, 15, 16, 17, and 18 show the device broken down into its main components;

Figure 19 and 20 show two enlarged views of the needle tip of the device, in which state tissue may protrude into the opening;

Figure 21 shows a cross-section along line *C-C*;

Figures 22, 23, and 24 show various views of a device in which the cover sleeve and the needle part are locked against each other by a compression spring device;

Figures 25 and 26 show the device broken down into its main components;

Figures 27 and 28 show a cross-section along line *D-D*;

Figure 30 shows a device in part in cross-section in which the needle may have a particularly small cross-section;

Figures 31, 32, 33, 34, and 35 show the device broken down into its main components;

Figures 36, 37, and 38 show three enlarged views of the tip of the device; the cover sleeve is depicted in cross-section in Figure 36;

Figure 39 shows an excision device, partly in cross-section, in which the cover part is rotated;

Figures 40, 41, 42, and 43 show the device broken down into its main components;

Figures 44 and 45 show two enlarged views of the needle tip.

In Figure 1, 2 represents the needle, 3 the cover sleeve, 4 the extractor, 5 the locking lever, and 6 the pin for the locking lever. The tip section of the device is shown in enlargement in Figure 8, but with retracted cover part. Figure 7 shows the tip in direction *D*; Figure 9 in direction *E*. Figure 8 represents the needle 2 and the cover sleeve 3. The needle 2 is implemented

with teeth 10 over a part of the internal surface of the cover section in order to prevent the tissue that is protruding into the cutout I from sliding out during excision. While the tissue biopsy is being cut, it slides into the cover sleeve 3. The cover sleeve 3 is slid back by the lever 5 and held such that its cutting edge 8 protrudes beyond the bottom part of the cutout. By cutting the tissue at the cutting-edge 8, the tissue also slides more easily into the lower section of the cutout I. If the cover sleeve is not held back such that it may be retracted whatever distance at will, the corresponding section of the needle may also be implemented such that it is able to cut. The cover sleeve is open at the rear so that no air buildup may occur while removing the tissue samples. If the cover sleeve 3 (Figure 3) is sharpened at its cutter, the base area 13 may be correspondingly sharpened at the needle 2 (Figure 2). The locking lever 5 (Figure 5) is implemented such that it locks the needle part and the cover part as represented in Figure 1 such that the cover sleeve holds the needle when it is introduced into the body, in particular when it punctures the skin. If the lever 5 is shifted, its lever part 11 is positioned above the cutout 12 of the cover sleeve 3. The cover part is now freely movable until the next mechanical stop (rear position). If the lever 5 is now brought back to its original position when the cover part is in a rear position, the cover part may be pulled out for the purpose of removing the sample that is attached to it. Instead of a lever 5, an automatically locking catch or the like that is activated by hand pressure may be used for the base position and for the rear position of the cover part.

Figure 11 shows a needle in which the cover sleeve 3 is provided with a cutter 14 running in the direction of the axis in order to prevent tissue buildup when removing tissue. Instead of the cover sleeve, the needle may be provided with a corresponding cutter. Figure 12 shows a cross-section along line *B-B*.

Figure 13 represents the needle 21 the holding device for the cover part 22, the cover sleeve 23, the clamp screw for the cover part 24, and hand screw 25. The intake space II of the needle tip of the device is partially enclosed by the needle for reasons of solidity because of the thin-walled components used for the needle. The cover sleeve 23 (Figure 16) is adjustable depending on its shortening by resharpening within the holding device 22 (Figure 15).

In Figures 22, 23, and 24, 43 represents the needle and 44 the cover sleeve. The cover sleeve may be retracted to the extent that it no longer protrudes into cutout III. Cutout III is implemented such that there is no obstruction as the tissue slides into it. In this embodiment of the invention, only the tip section of the needle cuts the tissue in cutout III as it slides in.

Figure 30 represents the needle 62, the cover sleeve 61, the holding device for the needle 63, the cone of the clamp 64, and the locking screw 65. The needle of the device may be produced with the smallest cross-section that is equal to that of the thinnest injection needle because of its simple and stable construction. The sample biopsy by such a device has a cross-section that is only a little smaller than the cross-section of the needle.

Figure 39 represents the needle 81 and the cover sleeve 82. The cover sleeve 82 may be rotated by 180°.

Patent claims:

1. Excision device for removing tissue samples from the human body, wherein said device is comprised in its main section of a needle and a cover sleeve, whereby the needle is comprised of a tube, a rod, or the like with a tip section that is rounded, pointed, or knife-shaped, and in addition is implemented with a cutout, notch, or opening or the like at its tip section for capturing tissue samples, while the tip section and the cutout or the like of the needle are implemented such that when the needle is inserted into the tissue, tissue must perforce enter into the cutout, which may be covered by the cover sleeve that is positioned at the needle in the direction of the longitudinal axis of same or rotated around the longitudinal axis of same, and whereby the tissue that protrudes into the cutout is cut off by its cutting edges.

2. Excision device according to claim 1, wherein the needle is also implemented with cutting edges for cutting the tissue sample.

3. Excision device according to claims 1 and 2, wherein the cutout of the needle is provided with hooks or ridges or the like.

4. Excision device for removing tissue samples from the human body according to claims 1, 2, and 3, wherein the needle part and the cover part may be connected to each other by a potentially symmetrically implemented lever, rotational, or spring mechanism or the like that is activated or triggered by hand in order to open the intake space, that is, move the needle or retract the cover part, or for closing the intake space, respectively, by means of the cover sleeve.

2 pages of diagrams

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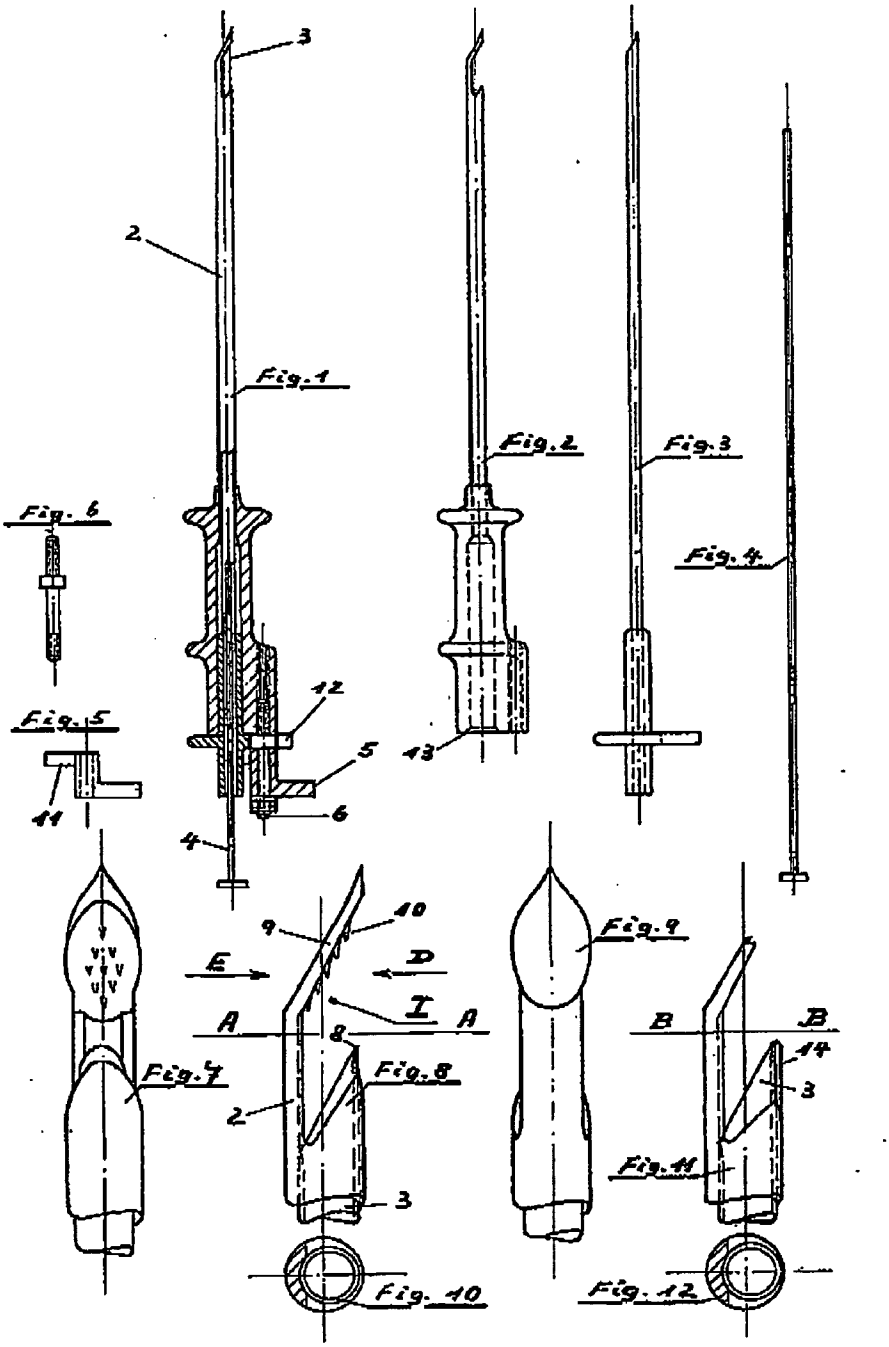

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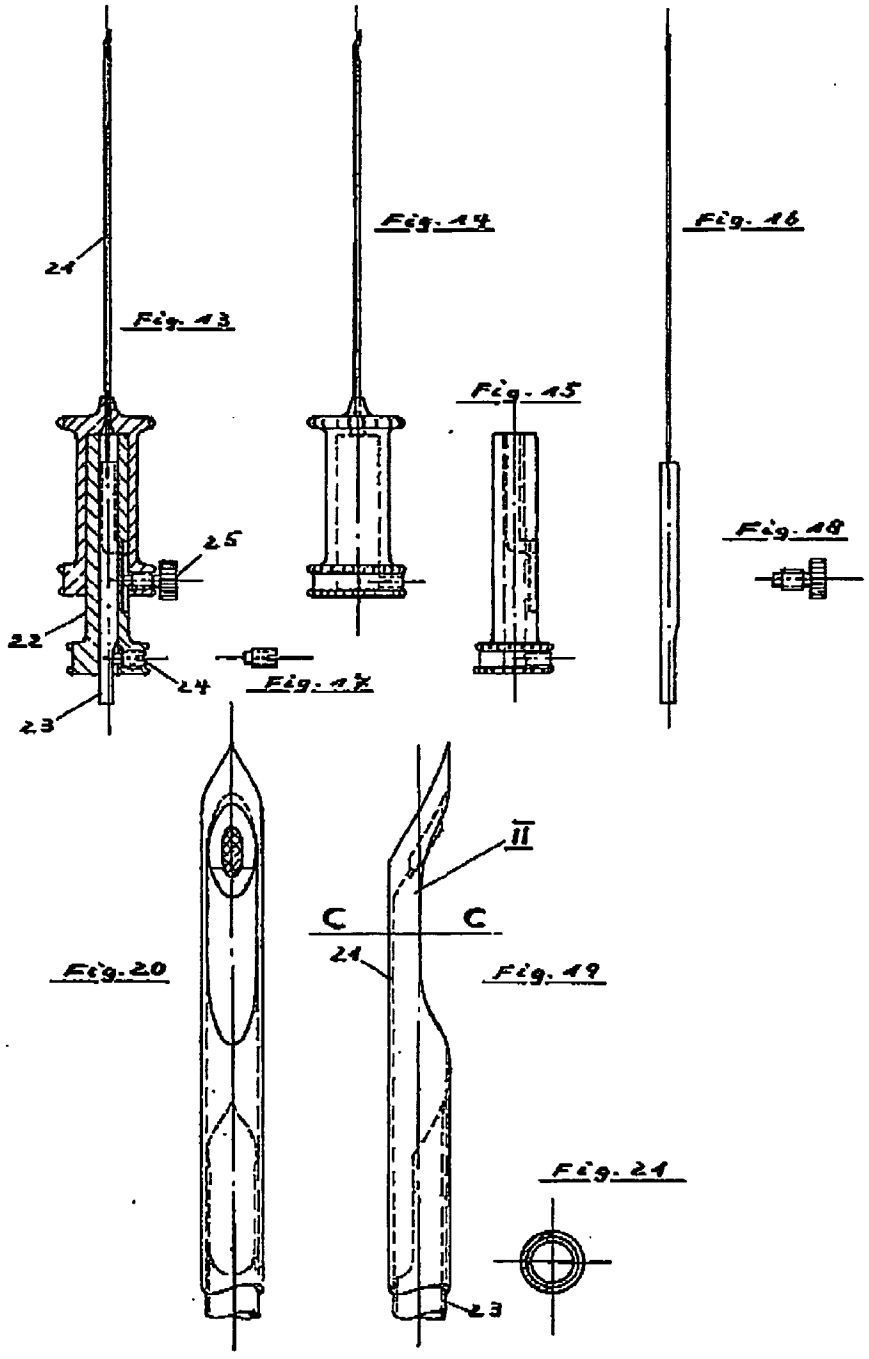

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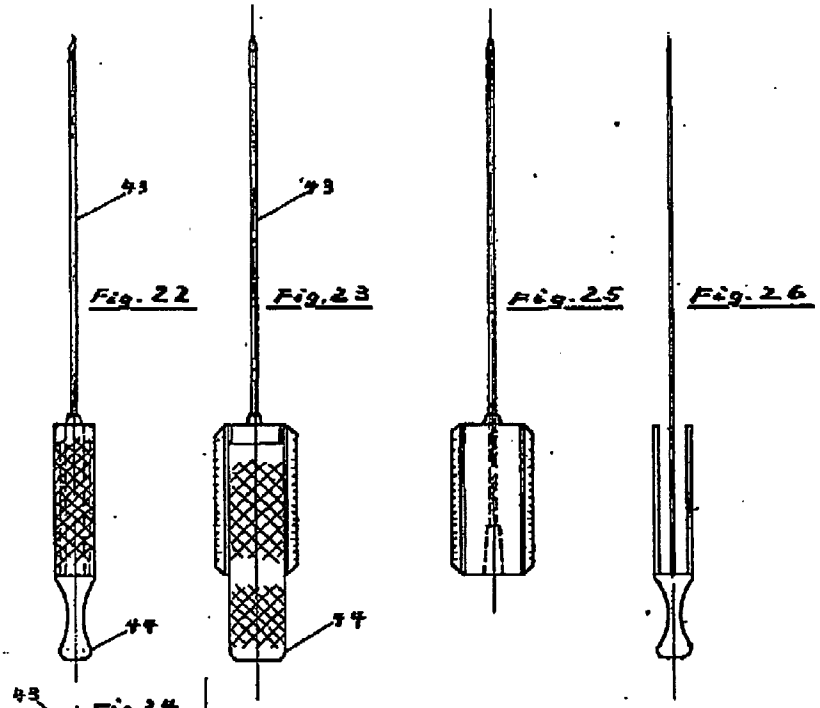

Fig. 22 Fig. 23 Fig. 25 Fig. 26

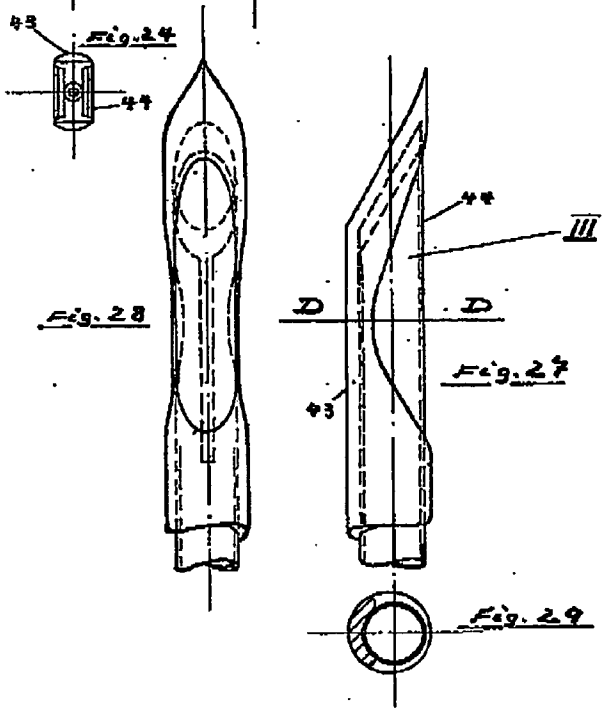

Fig. 24 Fig. 28 Fig. 27

Fig. 29

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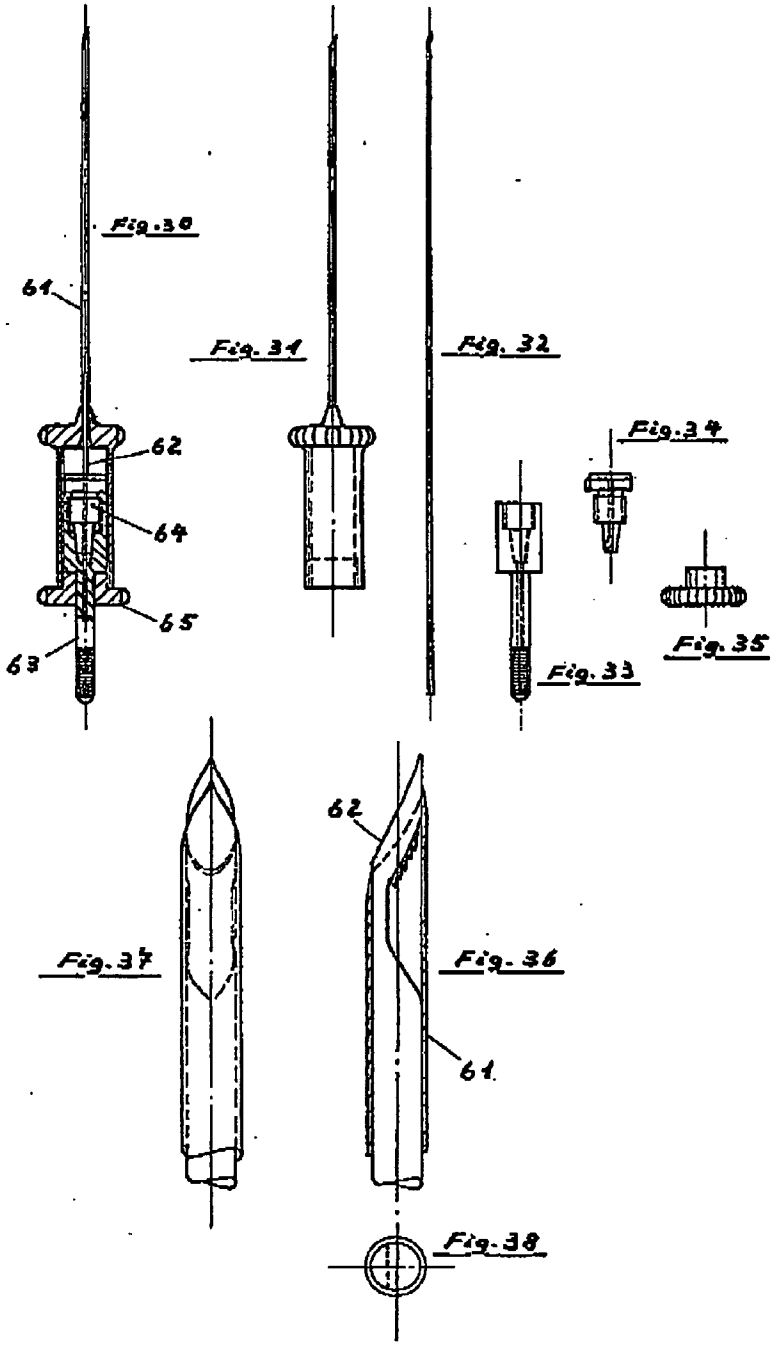

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